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1. Introduction and who the guideline applies to:

This guideline is intended for use by all medical, midwifery and nursing staff working in both Primary and Secondary care settings involved in the care of pregnant women and people and their families throughout screening and diagnosis of Hepatitis B in pregnancy.

Background:

These care pathways have been developed by the Multi-disciplinary Sexual Health Group to provide guidance for Maternity Unit staff involved in the care of pregnant women and people and their families with blood borne infections. The members of the Sexual Health Group are:

- Consultant Physician Genito-Urinary Medicine
- Consultant Obstetrician
- Consultant – Infectious Diseases
- Specialist Midwife - BBI
- Antenatal Screening Co-ordinator
- Pharmacist

There is a designated lead for antenatal screening for the UHL maternity service (Senior Midwife for Antenatal Services and Community), whose role it is to ensure appropriate processes are in place to offer pregnant women and people appropriate screening tests for blood borne infections in pregnancy as per National Screening Committee Guidance.

The following care pathways are available in this document:

Hepatitis B:

- Women's Services: Hepatitis B positive women. Antenatal & Postnatal management.
- Women's Services: Hepatitis B positive man. Antenatal & Postnatal management.
- Children's Services: Paediatric exposure to parental Hepatitis B surface antigen positive.

In addition, there are 3 care plans that are used by the Sexual Health Group. These care plans have been reproduced as part of this document for information but may be subject to changes by the Sexual Health Group. These care plans are to be commenced by the Sexual Health Group.

Perinatal Blood Borne Infection Care Plans:

- Hepatitis B Care Plan

Communication:

For any case that triggers the use of these care plans all relevant health professionals involved in the pregnant woman and persons care should be contacted and informed.

Related documents:

- Booking Bloods and Urine Test Guideline (UHL, 2018)
- Hepatitis C screening in Pregnancy Guideline (UHL, 2020)
- Missed antenatal appointments management guideline (UHL, 2019)

2. ANTENATAL MANAGEMENT OF ALL PREGNANT WOMEN AND PEOPLE:

All pregnant women and people should be offered screening for Hepatitis B infection by their midwife, ideally at booking or antenatally to provide the most appropriate clinical care and minimise risk of transmission to the baby; if screening is missed antenatally please offer intrapartum or postpartum and follow up accordingly.

This test should be considered an opt-out test, rather than an opt-in test:

- If screening is accepted, this must be documented within the Hand-Held Notes (Personal Maternity Record) by the person consenting the pregnant woman and person for the test.

- For full details of accurate completion of screening request forms and the management of rejected samples refer to the UHL booking bloods and urine tests guideline.

If screening is declined, the pregnant woman and person should be informed that they will be contacted by a specialist midwife at around 20 weeks to re-offer Infectious Diseases Screening.

All pregnant women and people who decline screening should have a form completed with documentation of her choice and submitted to the Lab. This should be documented in the maternity health record.

If screening is further declined, the reason should be documented in the Maternity Health records.

Consider offering repeat screening during pregnancy if test negative in 1st trimester, to exclude seroconversion, in those who have a continuing risk exposure, including pregnant women and people diagnosed with a sexually transmitted infection in pregnancy.

Hepatitis B infection is common in Leicester due to the multi-cultural diversity of our population. Most individuals with chronic hepatitis B infection acquired their infection abroad. All individuals with hepatitis B infection should be referred to the viral hepatitis service (run by Infectious diseases and Hepatology) for long-term monitoring and management.

High risk pregnant women and people/partners for hepatitis B infection:

- Pregnant women and people or their sexual partners who have lived in areas of the world where Hep B virus is endemic:
 - ~ Africa
 - ~ South-East Asia and India
 - ~ The Middle and Far East
 - ~ Some parts of Europe
- Pregnant women and people who have had medical or dental treatment abroad in a high prevalence area
- A blood transfusion abroad or pre 1985 in the UK
- Pregnant women and people who know or suspect that their partner is bisexual
- Known IV drug users, or whose partner is an IV drug user

2.1 Results

All screening tests for Hepatitis B in pregnancy must be seen by a qualified member of staff, communicated to the pregnant woman and person documented within the Maternity Health Record

2.2 Negative results for Hepatitis B

- The Community Midwife or Obstetrician who sees the pregnant woman and person at the next antenatal visit (at 14 -18 weeks gestation if possible), should check that the results of the Hepatitis B screening test are available, communicate the result to the pregnant woman and person and document the result in the Maternity Health Record ideally on the Maternity IT System.
- If the result is missing or not available, the health professional should check where the result is, and as a last resort consider repeat the screening test
- If the result is inconclusive, repeat the screening test, and discuss with virologist
- If the result is negative but the pregnant woman and person is at high risk of recent sexual acquisition, offer screening again at 28 weeks.

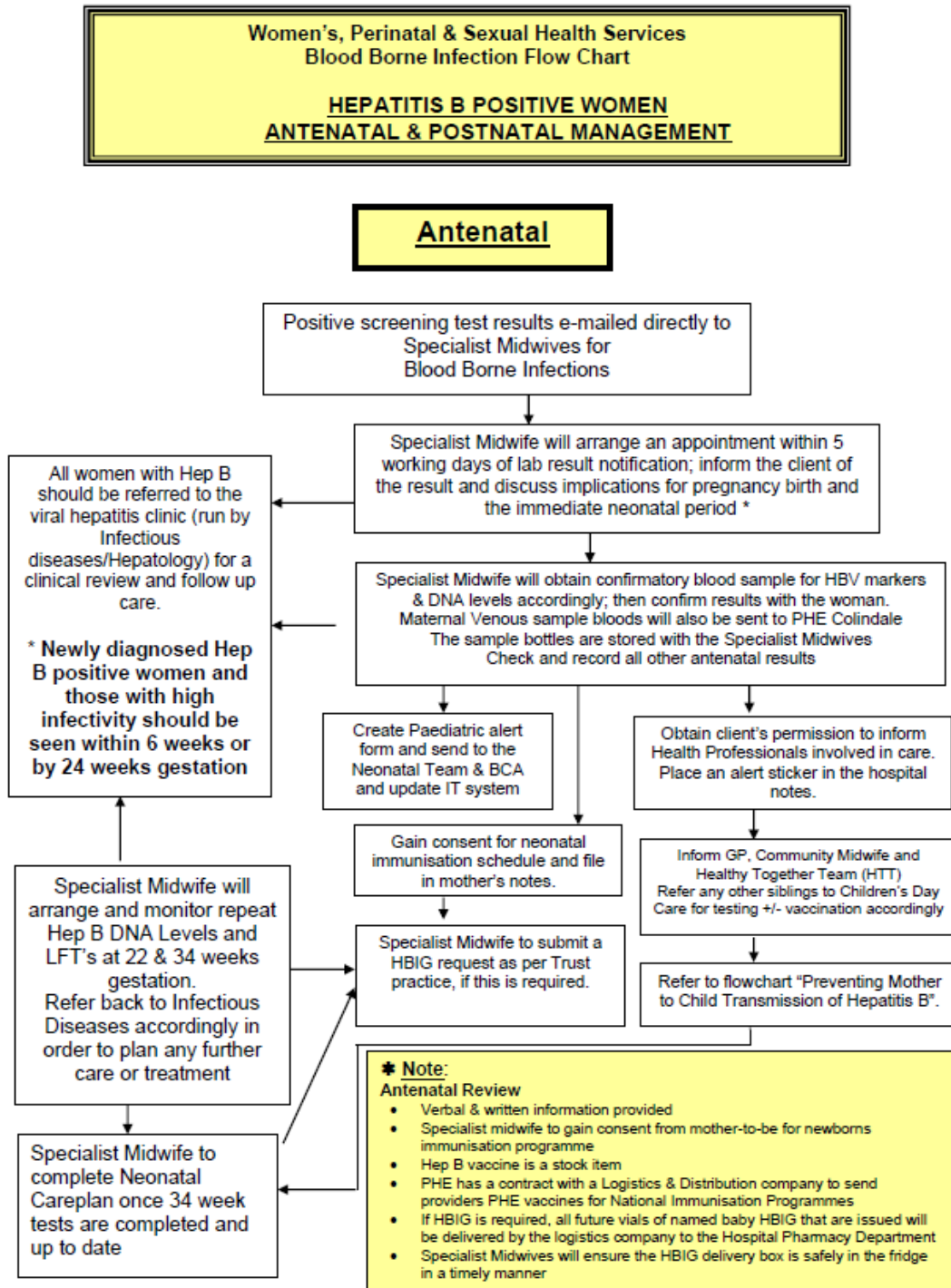
2.3 Positive results for Hepatitis B

- Positive results are e-mailed directly to the Midwife Specialist for Blood Borne Infections from the screening laboratory.
- The Midwife Specialist for Blood Borne Infections will contact the pregnant woman and person and arrange an appointment to give her the result within 5 working days.
- The Specialist Midwife will ensure that household contacts and partners are referred to their GP for testing as required.
- The Midwife Specialist for Blood Borne Infections will refer a newly diagnosed woman with Hepatitis B to a Hepatologist or Infectious Diseases Consultant, who will arrange an appointment for the pregnant woman and person to be seen within 6 weeks of diagnosis.
- The Midwife Specialist will also refer a pregnant woman and person with a high Hepatitis B DNA Level to the Hepatologist or Infectious Diseases Consultant; who will again arrange an appointment for the w pregnant woman and person to be seen within 6 weeks or sooner.
- If the partner is known to be Hepatitis B positive, a referral to the Specialist Midwives is required (see flow chart 2)
- For further advice on the management of positive results for Hepatitis B refer to the relevant pathways and care plans below.
- Pregnant women and people with a positive result who do not have an on-going pregnancy should still be seen by the specialist midwife and their results given and appropriate follow up arranged in the viral hepatitis clinic.

- If a pregnant woman and person presents late/unbooked in labour, please assess risk-factors and document a plan of care. All blood tests to be offered and results should be documented within 24 hours of the sample being taken or clear plan made to follow up the results (see Appendix1)
- Hepatitis C screening is not routinely performed in pregnancy but where indicated (after discussion with Infectious Disease Specialists) pregnant women and people who have a positive Hepatitis C screening test result should be managed following the Hepatitis C guideline and use the relevant care plans

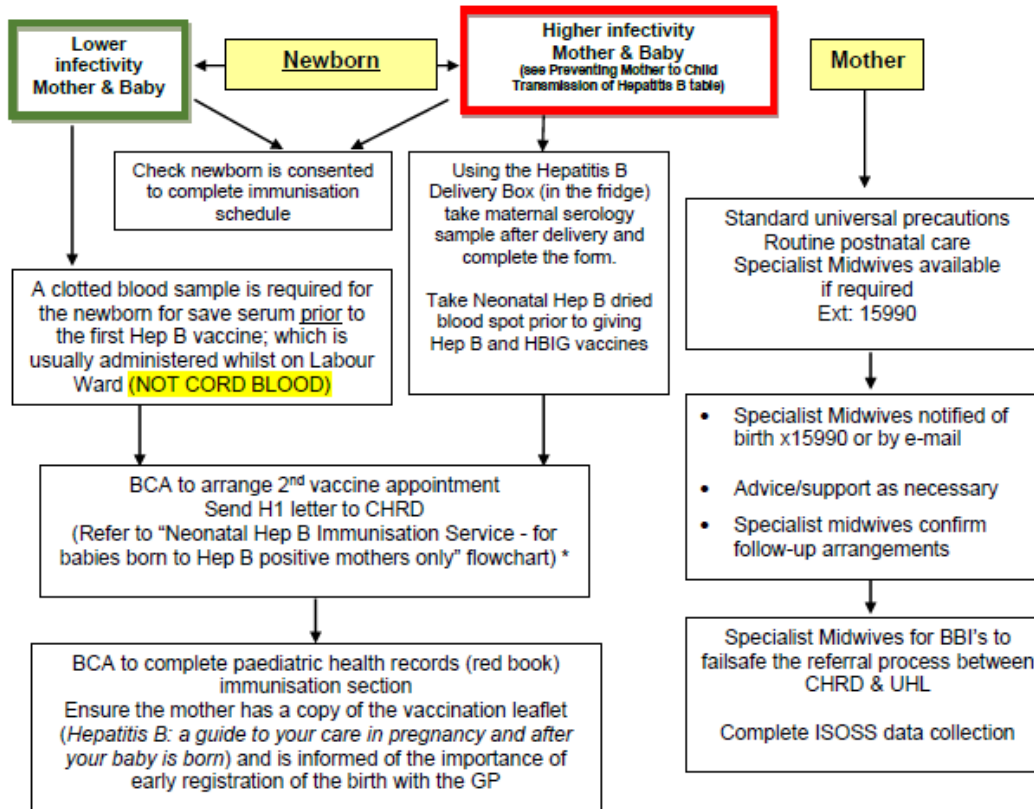
For further advice on the management of positive results for Hep B infection in pregnancy refer to the following flowcharts below.

Hepatitis B positive women, Antenatal & Postnatal management



**Women's, Perinatal & Sexual Health Services
Blood Borne Infection Flow Chart**

**HEPATITIS B POSITIVE WOMEN
ANTENATAL & POSTNATAL MANAGEMENT**



*** Note: Newborns Immunisation Schedule**

Monovalent Hepatitis B Vaccine at:

- Birth
- 1 month

Infanrix Hexa® routine childhood vaccination at:

- 2 months
- 3 months
- 4 months

Monovalent Hepatitis B booster at:

- 12 months

Blood Test also at:

- 12 months (Hep B dried blood spot)

Breast feeding - encouraged if full immunisation schedule to be completed

Contact details:

Specialist Midwives 0116 258 5990

Maxine Jethwa Maxine.Jethwa@uhl-tr.nhs.uk

Louise Boon Louise.boon@uhl-tr.nhs.uk

Mother HBsAg positive in pregnancy

Specialist Midwives review and repeat HBV DNA/Liver function tests: In first trimester
At 22 weeks gestation
At 34 weeks gestation

**Preventing Mother to Child
Transmission of Hepatitis B**

Table 1. Management of mother and infant according to serology and HBV DNA levels during pregnancy *

<u>Maternal serology</u>	<u>Maternal HBV DNA IU/ml</u>	<u>Maternal Tenofovir disoproxil (TDF) from 24 weeks gestation</u>	<u>Infant HBIG</u>	<u>Infant vaccination</u>
HBsAg positive; irrespective of eAg/Ab status	Any single level greater than 10 ⁶ during pregnancy	YES	See Table 2	See Table 3
HBeAg positive	Greater than 200,000	YES	YES	YES
HBeAg positive	Less than 200,000	X	YES	YES
HBeAg negative AND Anti-HBe (HBeAb) negative/equivocal	Greater than 200,000	YES	YES	YES
HBeAg negative AND Anti-HBe (HBeAb) negative/equivocal	Less than 200,000	X	YES	YES
HBeAg negative AND Anti-HBe (HBeAb) positive	Greater than 200,000	YES	X	YES
HBeAg negative AND Anti-HBe (HBeAb) positive	Less than 200,000	X	X	YES

Table 2 NEONATE HBIG schedule

Hepatitis B Immunoglobulin 250 IU at birth^{1,2}
PLUS
Hepatitis B vaccination^{1,2} in opposite limb at birth and further vaccinations as per Table 3

Table 3 NEONATE Hepatitis B vaccination schedule

Monovalent Hepatitis B Vaccine at:	Birth 1 month
Infanrix Hexa [®] routine childhood vaccination at:	2 months 3 months 4 months
Monovalent Hepatitis B booster at:	12 months
Dried Blood Spot Test also at:	12 months

*Any woman who has previously given birth to a baby who was subsequently found to be infected with Hepatitis B should also be considered for tenofovir disoproxil (TDF) therapy and their infant considered for Hepatitis B Immunoglobulin at birth¹.

¹Infants born to mothers who had acute Hepatitis B infection during pregnancy, or those born weighing less than 1500g should also receive Hepatitis B Immunoglobulin at birth, irrespective of the viral load or HBeAg of the mother².

In the above circumstances please contact phe.hepatitisbabies@nhs.net during office hours call 0330 128 1020-option 2. Out of hours Sat-Sun and bank holiday contact the Duty Doctor on 0208 327 7471.

Clinical advice is available from Infectious Diseases or Hepatology or Virology. Out of hours there is an Infectious Diseases consultant on call – contact main hospital switchboard.

Management of women prescribed anti-viral treatment for prevention of vertical transmission of Hepatitis B infection^{1,3}

Women who have conceived on anti-viral therapy should continue anti-viral treatment throughout pregnancy and beyond¹.

Women who have conceived on entecavir should be offered the option to switch to tenofovir disoproxil (TDF) during pregnancy as this is the preferred treatment option during pregnancy¹. Additionally, entecavir studies in animals have shown reproductive toxicity at high doses and the manufacturer recommends avoiding during pregnancy as the potential risk for humans is unknown.

Women who have conceived on tenofovir alafenamide (TAF) should be discussed directly with Infectious diseases or Hepatology for further advice as the use of this drug in pregnancy is not currently advised during the first trimester. Further data is required.

For women commencing TDF during pregnancy:

1. Start treatment at 24 weeks gestation and check HBV DNA at least once to ensure falling viraemia
2. Monitor renal function (in line with TDF SPC guidance³)
3. Aim to discontinue TDF by 12 weeks post-partum but ALT monitoring may be required to detect postnatal HBV flare

Safety in pregnancy^{1,4}

There is a considerable body of safety data from the Antiretroviral Pregnancy Registry for the use of TDF in pregnancy. The FDA considers it a Category B drug. Safety advice is supported by the British Viral Hepatitis Group guidelines.

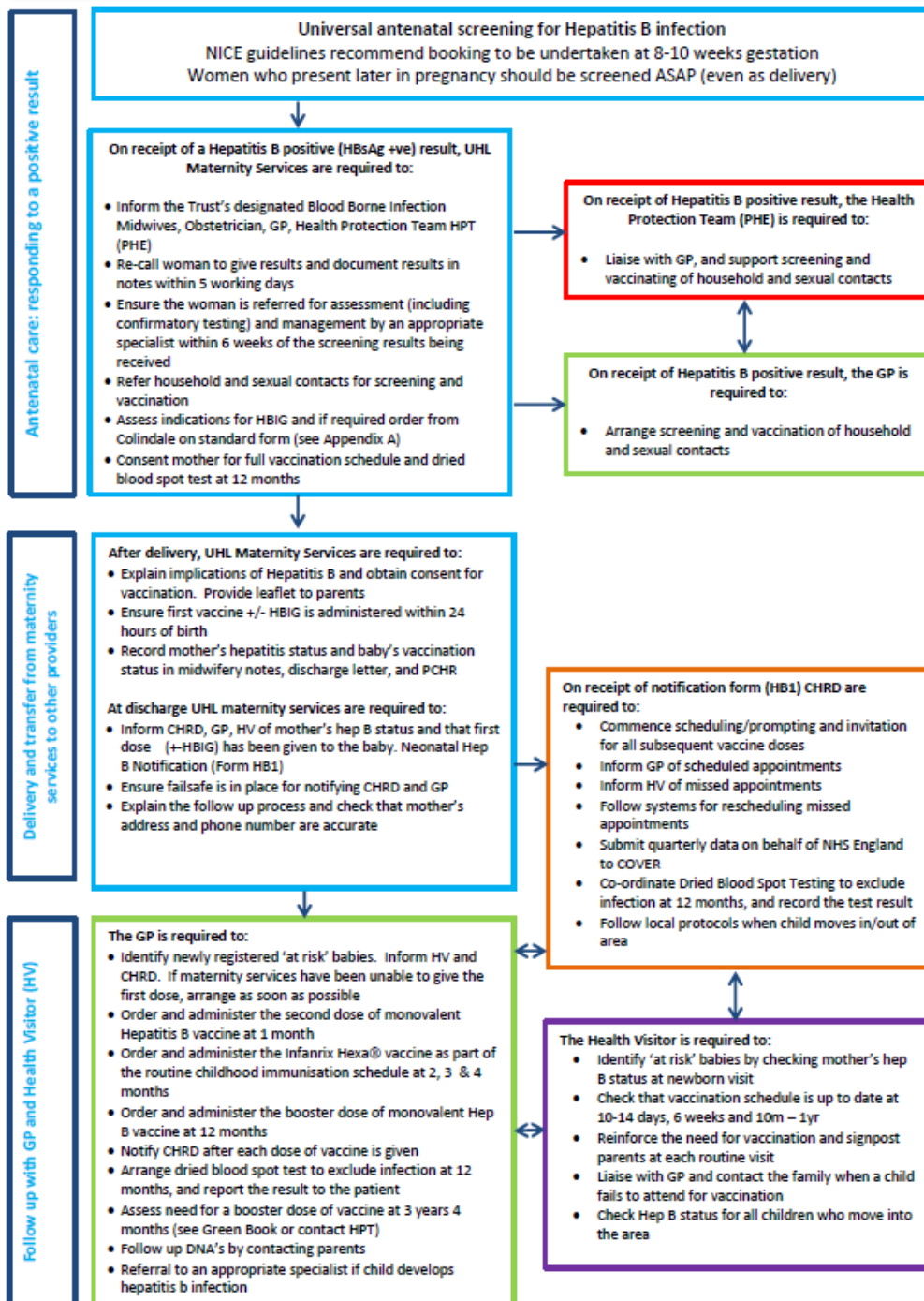
Breastfeeding advice^{1,5}

TDF is excreted in breast milk but in tiny amounts, considered insignificant. There is no current evidence of teratogenicity from its use in hepatitis B treatment in pregnancy. Current advice from the UK Drugs in Breast Milk Advisory Service (based in Leicester) is that the benefits of breastfeeding outweigh any risks from TDF in this setting. This view is supported by the British Viral Hepatitis Group guidelines, provided that the infant is vaccinated from birth.

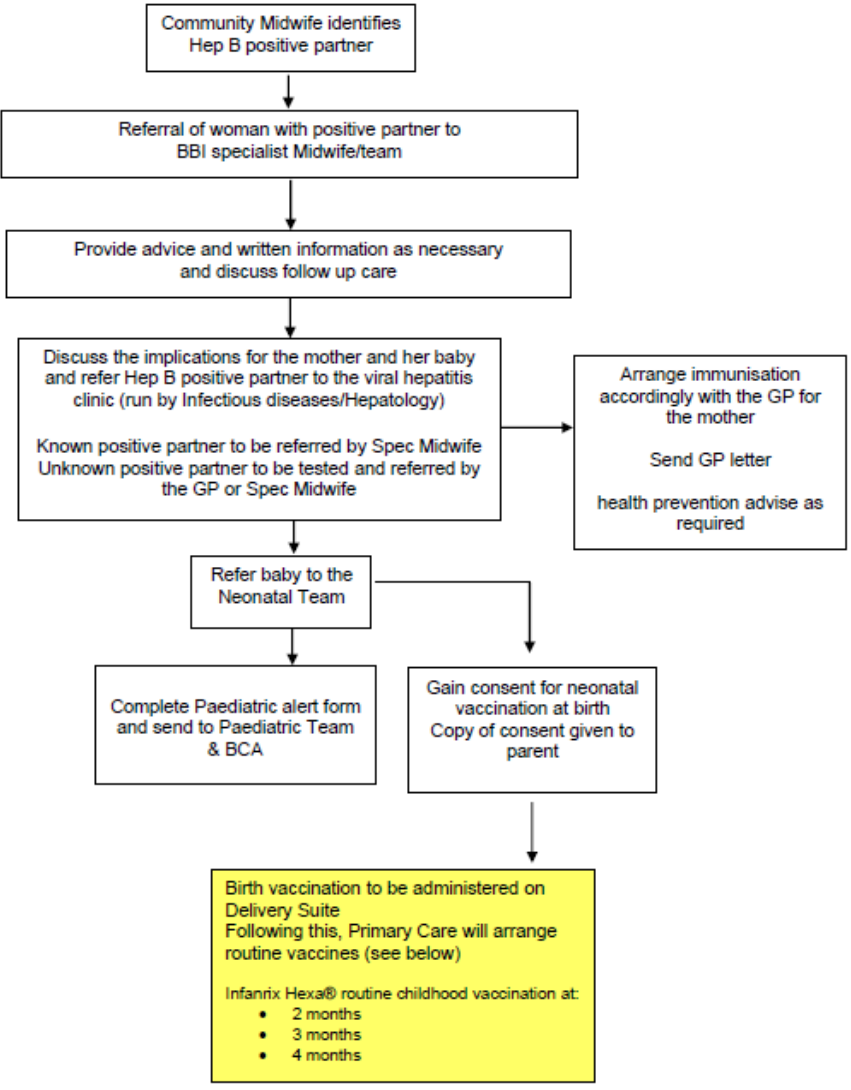
References

1. British Viral Hepatitis Group. Guideline for the management of hepatitis B in pregnancy and the exposed infant 2021. [BVHG Perinatal HBV 3.3.21.pdf \(basl.org.uk\)](#)
2. Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway. Published 8th January 2021. [Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway - GOV.UK \(www.gov.uk\)](#)
3. Summary of Product Characteristics. Tenofovir disoproxil 245mg tablets. Available from: <https://www.medicines.org.uk/emc/medicine/9008>
4. The Antiretroviral Pregnancy Registry Interim Report 1 January 1989 through 31 January 2022. http://apregistry.com/forms/interim_report.pdf
5. UK Drugs in Breast Milk Advisory Service (personal correspondence)

Neonatal Hepatitis B Immunisation Service for babies born to Hepatitis B positive mothers only



Women's, Perinatal & Sexual Health Services
Blood Borne Infection Flow Chart
HEPATITIS B POSITIVE PARTNER
ANTENATAL & POSTNATAL MANAGEMENT



Perinatal Blood Borne Infection Care Plan

Hepatitis B

Intrapartum Care Plan

*Aim for vaginal delivery

Managed actively as below, unless obstetric indication for caesarean section

Check if there is an individualised careplan for this woman.

- Await spontaneous labour unless obstetric indication to intervene
- Active management of the 3rd stage of labour

Please note:

Although interventions in labour should be avoided where possible e.g. the use of fetal scalp electrodes/fetal blood sampling; to reduce the risk of transmission of infection to the baby, they are not absolutely contraindicated and so can be considered following a discussion with the Obstetric Consultant. ¹

If Pre-labour Rupture of Membranes

1. Be certain of diagnosis
2. Induce / augment immediately using Oxytocin and/or Prostin
3. If signs of infection refer to the Sepsis UHL Pathway.

- On admission to Delivery Suite inform BBI Specialist Midwives of patients' admission.
- Neither cord blood or placental pathology is routinely required.
- Bath baby following birth on Delivery Suite
- *Please note the Delivery Box for those baby's requiring HBIG is stored in the NNU fridge LGH, D/Suite fridge LRI*

If >34 weeks augment labour as soon as possible

If <34 weeks seek specialist advice

In certain circumstances for example high Hepatitis B DNA levels, prematurity (<34weeks) and pre-rupture of membranes seek advice from Hepatology or Infectious Diseases Physician & Consultant Obstetrician.

*Individualised Plan

Sign: _____ Print name: _____ Date: _____

Perinatal Blood Borne Infection Care Plan

Hepatitis B

Neonatal Care Plan

*Neonatal Management – Hepatitis B Immunisation Schedule

Paediatric responsibility following delivery

Dear Doctor

My baby requires Hepatitis B vaccine immediately after birth, administered on Delivery Suite, or as soon as possible after birth (within 24 hours).

*A clotted blood sample is usually taken from my baby for save serum prior to giving the birth vaccine.

- Please note I was already on treatment for Hepatitis B when I became pregnant Yes No
*Low infectivity
High infectivity - see below
Hepatitis B flare in pregnancy - see below
- I started treatment for Hepatitis B in this pregnancy as per guideline Yes No
- My baby also requires HBIG injection (250 IU) immediately after birth, along with the Hepatitis B vaccine (Refer to the individualised Hep B Delivery Box in fridge) Yes No

If Yes:

- 1 - Obtain Maternal Virology sample after delivery and complete the request form which is in the delivery box
- 2 - Take Neonatal dried blood spot prior to vaccination and complete paperwork and send
- 3 - Give Hep B vaccine and HBIG (consent form will be usually filed in the woman's maternity notes)

*Please note:

Pre-term Babies of Hepatitis B positive mothers: It is important that premature infants receive the full paediatric dose of Hepatitis B vaccine on schedule (within 24hrs) according to the mother's Hepatitis B markers (see 'Preventing Mother to Child Transmission of Hepatitis B guidance')

Low Birth Weight Babies: Babies born to mothers infected with Hepatitis B, with a birth weight of $\leq 1500g$ should receive Hepatitis B immunoglobulin immediately after birth in addition to the vaccine, irrespective of the viral load or HBeAg status of the mother (see Preventing 'Mother to Child Transmission of Hepatitis B' guidance).

- In the event that a supply of HBIG has not yet been made, contact the phe.hepatitisbabies@nhs.net during office hours call 0330 128 1020- Option 2. HBIG request form will need to be completed and sent to the above e-mail address.
- Out of hours Sat-Sun and bank holiday contact the Duty Doctor on 0208 327 7471.

As per the Green Book, Hepatitis B chapter: if muscle mass is too small to infiltrate in one site, the immunoglobulin should be divided into smaller amounts and administered into different sites. HBIG may be administered, at a different site, at the same time as the Hepatitis B vaccine. The HBIG request form that comes with the vial.

**If baby is very low birth weight and clinical decision made to give divided doses, please record when the second part of the dose was given (should be given as soon as possible)*

Whilst we have not recommended or published any guidance on this (other than give as soon as possible), if some Neonatologists decide to give it over a couple days so to not disrupt fluid balance – this will need to be documented so that the outcome can be audited.

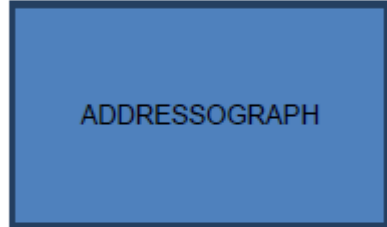
*Individualised Notes:

Sign: _____ Print Name: _____ Date: _____

- The Newborn accelerated immunisation is Monovalent Hepatitis B vaccine at: Birth and 1 Month. Then routine childhood immunisation schedule with Infanrix Hexa® at 2 months, 3 months and 4 months. Then Monovalent Hepatitis B Booster Vaccine at 12 months and dried blood spot test at 12 months.
- If HBIG is required (Hepatitis B Immunoglobulin) this is given to my baby at the time of first Hepatitis B vaccine (IN OPPOSITE THIGH).
- Hepatitis B immunisation (HBIG) box is ordered by Specialist Midwives Louise Boon and Maxine Jethwa, Ext: 15990. It is stored in the fridge on Delivery Suite at the LRI or the NNU fridge at the LGH (HBIG will be issued 7 weeks prior to the EDD).
- Breast feeding is encouraged if full vaccination schedule to be completed.
- Complete H1 form and send to CHRD with a copy to the GP, Medical notes and Specialist Midwives.
- BCA's to inform Specialist Midwives of delivery by e-mail
- Primary Care to complete immunisation schedule.

4

CHECKLIST FOR UNBOOKED WOMEN presenting in labour or at advanced gestation.



- Obtain obstetric/medical history, assess risk factors and document a plan of care.
- Appropriately qualified doctor to perform portable ultrasound scan to assess placental localisation and presentation and biometry if possible.
- Consider use of continuous Fetal monitoring in labour.
- Postnatally–
 - commence NEWS chart for baby observations due to the high mortality rate in this group of neonates.
 - All babies born to “unbooked” women should have a paediatric check prior to discharge.
 - Consider any safeguarding concerns.
- All Blood tests to be offered and taken as follows:

Blood test required	Sample bottle	Form	Sign & date when sample taken	Sign and date result received
FBC	Red EDTA 4.9ml	UHL Combined haematology/pathology		
Group & Save	Red or blue EDTA 7.5ml	UHL Blood transfusion		
HIV point of care test	Point of care test kit on delivery suite	Document in notes if this was offered but declined by patient		
Virology –URGENT request for HIV, Hep B, Syphilis	White/black label	UHL virology		
Haemoglobinopathy screening	Purple bottle	Dedicated UHL antenatal family origin questionnaire form – can be accessed on ICE		

PLEASE NOTE - ALL BLOOD RESULTS SHOULD BE DOCUMENTED WITHIN 24 HOURS OF THE SAMPLE BEING TAKEN or a clear plan made to follow up results.

3. Education and Training:

Antenatal Screening Session on Mandatory Training Day

4. Monitoring Compliance:

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
All women were offered screening for Hepatitis B and this was documented in the health record	Antenatal screening KPI's	AN screening co-ordinator and specialist midwives	Quarterly	NSC
All women that consent to Hep B & screening receive a conclusive result or are informed if the sample is not processed and repeat screening is offered even if they miscarry	Antenatal screening KPI's	AN screening co-ordinator and specialist midwives	Quarterly	NSC
All high-risk results were telephoned to the Specialist Midwife	Monthly failsafe checking between the Lab, antenatal screening and specialist midwifery	AN screening co-ordinator and specialist midwives	Monthly	Internal database maintained
All women who had screen positive test results for Hepatitis B were seen by the Specialist Midwife, her results reviewed and the woman informed of the positive result within 5 working days of the result being available	Annual IDPS data return to PHE	AN screening co-ordinator and specialist midwives	Annually	NSC
All positive results are clearly documented in the woman's records	Screening audits for QA review	AN screening co-ordinator and specialist midwives	Triennially	PHE QA team
All notes of woman with a positive result had an alert sticker on the front cover of the hospital notes	Screening audits for QA review	AN screening co-ordinator and specialist midwives	Triennially	PHE QA team
All women with a positive result had a Hepatitis B Care Plan completed and this is filed in the health record	Screening audits for QA review	AN screening co-ordinator and specialist midwives	Triennially	PHE QA team

5. Supporting References

6. Key Words

1. British Viral Hepatitis Group. Guideline for the management of hepatitis B in pregnancy and the exposed infant 2021. [BVHG Perinatal HBV 3.3.21.pdf \(bvlg.org.uk\)](https://www.bvlg.org.uk/wp-content/uploads/2021/01/BVHG_Perinatal_HBV_3.3.21.pdf)
2. Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway. Published 8th January 2021. [Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/9008/guidance-on-hepatitis-b-antenatal-screening-and-selective-neonatal-immunisation-pathway.pdf)
3. Summary of Product Characteristics. Tenofovir disoproxil 245mg tablets. Available from: <https://www.medicines.org.uk/emc/medicine/9008>
4. The Antiretroviral Pregnancy Registry Interim Report 1 January 1989 through 31 January 2022. http://apregistry.com/forms/interim_report.pdf
5. UK Drugs in Breast Milk Advisory Service (personal correspondence)

Hepatitis B, Infection, Sexual Health, Virology,

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Author / Lead Officer: Written: September 2011		Sexual Health Group; Specialist Midwives and Consultants in GU medicine	Executive Lead: Chief Nurse
Feb.15	1	Sexual Health Group	New process for arranging and administering Hep Vaccination to babies born to hep B positive mothers More accurate flowcharts describing the antenatal/postnatal and positive partner processes Contact details have altered Updated careplans and brought into line with other BBI careplans in pregnancy
Nov 16	2		Related "missed antenatal appointments guideline added" Changes in national recommendations for women who decline screening Addition of the management of positive results for women who miscarry or have a termination of pregnancy
February 2018	3		Hepatitis B doses in the immunisation schedule for routine childhood and selective neonatal Hepatitis B programmes have been reviewed and updated. Hepatitis B virus infection and your baby leaflets for patients have been updated and reprinted. Generic inbox for emailed positive results now active for the team. Syphilis care plan and template amended.
January 2020	4	As above	Careplan updated
December 2023	5	H White – Consultant S Bandi – Consultant L Boon – Specialist Midwife M Jethwa – Specialist Midwife	Separated from syphilis guideline Acknowledgment of local prevalence Updated high risk criteria Amended statement; 'the result is negative but the woman is from the "high risk" (as detailed above), offer screening again at 28 weeks' to 'If the result is negative but the woman is at high risk of recent sexual acquisition, offer screening again at 28 weeks.' Positive results to be communicated to the woman within 5 days, previously this was 10 days. Hepatitis screening option where indicated added. Actions following positive result flow chart updated. A/N & P/N management of mother and newborn updated and separated to low and high chance of infectivity pathways. Reference to Hep B box in fridge on labour ward/delivery suite. Preventing mother to child transmission flow chart converted to table. Repeat HBV DNA/LFT changed from at 26/40 to 22/40 Management of Tenofovir treatment changed, to start at

			<p>24/40 rather than 28-30/40 7 continue for up to 12 weeks P/N rather than one month.</p> <p>Hep B positive partner pathway updated to notify GP</p> <p>FBS not absolutely contraindicated and should be discussed with obstetric consultant.</p> <p>Specialist midwives to be informed if admitted with pre labour rupture of membranes.</p> <p>Reference made to delivery suite box for baby.</p> <p>Hep B neonatal care plan added reference to low and high infectivity, and premature infants require the full paediatric dose of Hep B vaccine.</p>
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